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| 10/789,967 | 02/27/2004 | Joseph Anthony Gatto | 8725R2R | 9429 |

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THE PROCTER & GAMBLE COMPANY
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| EXAMINER |
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PALLAY, MICHAEL B

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1617

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01/12/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/789,967 | Applicant(s) GATTO, JOSEPH ANTHONY | |
| | Examiner MICHAEL PALLAY | Art Unit 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-18 and 20-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-18 and 20-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 23, 2010, in which claims 13, 18, 26, and 27 were amended, has been entered. Accordingly, claims 11-18 and 20-27 are pending in the application.

Change of Examiner

The examiner assigned to the instant application has changed. The new examiner is Michael Pallay. Contact information is provided at the end of this Office Action.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional

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application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosures of the prior-filed applications, Application Nos. 10/444,241, 10/152,924, and 09/968,154, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. None of the aforementioned applications disclose a method for preparing a lotion for reliable high speed processing onto a substrate that includes the step of milling the premix solution into a carrier system at a temperature of at least about 35 degrees C to disperse the premix solution until an average droplet diameter of the dispersed premix solution is less than about 100 microns to form the lotion, which is recited in claim 11 of the instant application (upon which all other claims depend). Accordingly, claims 11-18 and 20-27 are not entitled to the benefit of the aforementioned prior applications.

Furthermore, "each prior-filed application must name as an inventor at least one inventor named in the later-filed application." 37 CFR 1.78(a)(1). Joseph Anthony Gatto is the sole inventor named in the instant application, but he is not a named inventor in Application Nos. 10/152,924 or 09/968,154. Accordingly, claims 11-18 and 20-27 are not entitled to the benefit of Application Nos. 10/152,924 or 09/968,154.

Therefore, the effective filing date of claims 11-18 and 20-27 of the instant application is February 27, 2004, the actual filing date of the instant application.

Claim Rejections - 35 USC § 112 Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-18 and 20-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "about" in claims 11, 13, 15-18, 26, and 27 is a relative term which renders the claims indefinite. The term "about" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The claims, specification, and prosecution history fail to define what is meant by the term "about" and how much variation above and below the recited temperatures, numbers of carbon atoms, and average droplet diameter is encompassed by the claim recitations, and therefore the resulting claims do not clearly set forth the metes and bounds of the patent protection desired. As noted in MPEP 2173.05(b), "claims reciting 'at least about' were invalid for indefiniteness where there was close prior art and there was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term 'about.' *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991)." Claims 12, 14, and 20-25 are rejected as depending on indefinite base claims.

Response to Arguments

The prior Office Action dated April 27, 2010, rejected claims 11-18 and 20-27 as indefinite because it is unclear what controls the metes and bounds of the phrases “at least about,” “less than about,” and “from about” (pages 3-4). The Office Action notes that applicant has failed to provide a definition for the term “about” in the instant specification, such that there is no indication or hint as to what amount of variation above or below the recited temperature and droplet diameter would constitute infringement of the instant claims, and there is nothing in the specification or prosecution history that provides any indication as to what amount of variation is tolerated by the term “about” (page 4).

In response thereto, applicant amended claims 13, 26, and 27 to remove the term “from.” Applicant argues that recitations of the above phrases in the specification are consistent with the recitations in the claims, and that a person having ordinary skill in the art, having read the specification, would have no difficulty measuring the temperature and diameter or interpreting the phrases (pages 7-8). Applicant also notes that there is no per se rule that open-ended numerical ranges are indefinite and cites MPEP 2173.05(c) in support thereof (page 8).

Applicant’s amendments do not cure the indefiniteness of the claims, nor are applicant’s arguments found persuasive. The amendments do not remove the term “about” from the claims, and therefore the amended claims are still indefinite. The fact that the phrases are consistent with recitations in the specification is irrelevant because the term “about” is not defined in the specification, claims, or prosecution history. The

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fact that there is no per se rule that open-ended numerical ranges are indefinite is also irrelevant because the issue at hand concerns relative terminology as discussed in MPEP 2173.05(b) rather than open-ended numerical ranges as discussed in MPEP 2173.05(c). The paragraph cited from the MPEP by applicant does not even mention the term "about." To the extent that the previous Office Action rejected the claims as indefinite because, among other reasons, one of ordinary skill could not determine which term is in control within each of the above-mentioned phrases, such reasoning is not relied upon in this Office Action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-18 and 20-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammons et al. (WO 03/028776 A1; published April 10, 2003) in view of Klofta et al. (US 2002/0165508 A1; published November 7, 2002).

Claim 11 encompasses a method for preparing a lotion for reliable high speed processing onto a substrate, the method comprising the steps of: (a) providing a carrier system; (b) mixing a premix solution comprising niacinamide and a material selected from the group consisting of glycerin, propylene glycol, panthenol, and mixtures thereof, at a temperature of at least about 35 degrees C; and (c) milling the premix solution into

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the carrier system at a temperature of at least about 35 degrees C to disperse the premix solution until an average droplet diameter of the dispersed premix solution is less than about 100 microns to form said lotion.

Hammons et al. disclose a lotion composition applied to a catamenial device such as a sanitary napkin (abstract; page 1, line 10) wherein the lotion composition is formulated by combining a carrier or carrier system with skin treatment agents (page 14, lines 10-20). The skin treatment agents include niacinamide, hexamidine, zinc oxide, and combinations thereof (page 6, lines 21-29). The niacinamide skin treatment agent provides for skin conditioning benefits as well as providing for increased efficacy of the skin treatment agents in controlling skin disorders (page 9, line 26 to page 10, line 2). Glycerine may optionally be added as a dispersing agent for the niacinamide and as a skin conditioning agent and for skin emolliency benefits such as smooth, soothing, and soft feeling skin (page 13, lines 19-24). Panthenol may also optionally be added as a skin conditioning agent that provides for skin emolliency benefits that can leave the skin feeling smooth, soothing, and soft during and after interaction of the skin tissues with skin treatment agents (page 13, lines 1-7).

Examples II, III, and IX of Hammons et al. specifically disclose lotion compositions containing both niacinamide and glycerine (pages 27-28; table 2). The lotion is prepared by first making a carrier system, then mixing the skin treatment agents and any optional ingredients such as optional skin conditioning agents at a temperature of about 80°C, wherein carrier system, skin treatment agents, and any optional ingredients are processed at a temperature of about 80°C (page 23, lines 11-23).

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Examples II-IX are prepared by formulating a premix solution of zinc oxide skin treatment agent and adding the premix to the other skin treatment agents and any optional ingredients such as panthenol and glycerin, or by formulating a skin treatment solution of hexamidine and niacinamide skin treatment agents and any optional ingredients (page 27, lines 3-9). The skin treatment solution is then added to a carrier solution, wherein the skin treatment solution and carrier system is heated while stirring to a temperature of about 80°C (page 27, lines 9-11). Hammons et al. do not disclose the step of milling the premix solution into the carrier system to disperse the premix solution until an average droplet diameter of the dispersed premix solution is less than about 100 microns. However, such was known in the prior art.

Klofta et al. disclose an absorbent product such as a sanitary napkin having a stable skin care composition disposed on a portion of its skin-contacting surface (paragraphs [0002], [0020]). The composition may include emollients or skin protectants such as petrolatum, glycerin, or propylene glycol (paragraphs [0092], [0093]). Klofta et al. teach, "It is generally known that solid particles in neat form tend to form clumps or agglomerates, bound by static charges, interactions between functional groups, etc. It is often necessary to break up the clumps in order to disperse the particles, to reduce the settling effect, and to deliver skin benefits effectively. The break-up and dispersion can be accomplished by grinding or milling, by incorporation into a composition with agitation, by predispersing in a dispersant mixture, by predissolving in a carrier or by other methods known to persons skilled in the art." (paragraph [0062]). Klofta et al. further teach that various grinding and/or milling

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techniques known in the art are sometimes used in the predispersing process to break down the particle size and disperse the particles (paragraph [0063]). As an example, Klofta et al. disclose zinc oxide dispersed in a dispersant fluid where the average particle size is about 0.12 microns and the average agglomerate size is about 1.0 microns (paragraph [0064]). Klofta et al. further teach the use of propylene glycol or glycerine as suitable solvents that are well known in the art as additives for lotions and other similar compositions (paragraph [0137]). Klofta et al. thereby cure the deficiency of Hammons et al. by teaching the step of milling during dispersion of a substance in a lotion to be disposed on an absorbent product such as a sanitary napkin in order to break down particle size and disperse the particles, such that the average particle size is about 0.12 microns and the average agglomerate size is about 1.0 microns.

Claim 12 encompasses the method of claim 11, wherein the carrier system comprises petrolatum. Hammons et al. specifically disclose petrolatum as a suitable carrier (page 15, lines 7-15; Example 1; Table 1). Klofta et al. also specifically disclose the use of petrolatum (Examples 1-6).

Claim 13 encompasses the method of claim 12, wherein the carrier system further comprises fatty alcohols having about 12 to about 24 carbon atoms, alkyl ethoxylates, fumed silica, talc, bentonites, hectorites, calcium silicates, magnesium silicates, magnesium aluminum silicates, zinc stearates, sorbitol, colloidal silicone dioxides, spermaceti, carnuba wax, beeswax, candelilla wax, paraffin wax, microcrystalline wax, castrol wax, ceresin, esparto, ouricuri, rezowax, polyethylene wax, C12-C24 fatty acids, polyhydroxy fatty acid esters, polyhydroxy fatty acid amides,

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polymethacrylate polymers, polymethacrylate and styrene copolymers, or combinations thereof. Hammons et al. specifically disclose all of these compounds as suitable carriers (page 14, lines 21-30; page 17, lines 11-19).

Claim 14 encompasses the method of claim 12, wherein the carrier system further comprises a skin treatment active selected from the group consisting of allantoin, aluminum hydroxide gel, calamine, cysteine hydrochloride, racemic methionine, sodium bicarbonate, Vitamin C, serine protease, metalloprotease, cysteine protease, aspartyl protease, peptidase, phenylsulfonyl fluoride, lipase, diesterase, urease, amylase, elastase, nuclease, guanidinobenzoic acid and its salts and derivatives, chamomile, and mixtures thereof. Hammons et al. specifically disclose all of these compounds as suitable skin treatment actives (page 10, line 27 to page 11, line 6). Klofta et al. also specifically disclose skin care ingredients that can be incorporated into the carrier such as allantoin, aluminum hydroxide gel, calamine, cysteine hydrochloride, racemic methionine, sodium bicarbonate, serine proteases, metalloproteases, cysteine proteases, aspartyl protease, peptidases, lipases, diesterases, ureases, amylases, elastases, and nucleases (paragraphs [0053], [0055], [0057], [0058]).

Claim 15 encompasses the method of claim 11, wherein the solution is mixed at a temperature of at least about 50 degrees C. Hammons et al. disclose mixing the skin treatment agents, such as niacinamide, and any optional ingredients, such as glycerin and panthenol, at a temperature of about 80°C (page 23, lines 11-23; page 13, lines 1-7 and 19-24).

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Claim 16 encompasses the method of claim 11, wherein the solution is mixed at a temperature of at least about 80 degrees C. Hammons et al. disclose mixing the skin treatment agents, such as niacinamide, and any optional ingredients, such as glycerin and panthenol, at a temperature of about 80°C (page 23, lines 11-23; page 13, lines 1-7 and 19-24).

Claim 17 encompasses the method of claim 11, wherein the milling is at a temperature of at least about 50 degrees C. Hammons et al. teach that the skin treatment solution is added to the carrier solution at a temperature of about 80°C (page 27, lines 9-11). Furthermore, Klofta et al. specifically disclose use of a mill when adding the predispersion to the petrolatum carrier at a temperature of about 77° C (Example 1; paragraph [0200]).

Claim 18 encompasses the method of claim 11, wherein the milling step continues until the average droplet diameter of the dispersed premix solution is less than about 50 microns. Klofta et al. disclose an average particle size of about 0.12 microns and an average agglomerate size of about 1.0 microns of the dispersed premix (paragraph [0064]).

Claim 20 encompasses a disposable absorbent article comprising a lotion made according to the method of claim 11, wherein said disposable article is selected from the group consisting of diapers, sanitary napkins, panty liners, and incontinence briefs. Hammons et al. specifically disclose application of the lotion to catamenial devices such as sanitary napkins, pantyliners, and sanitary pads (page 4, lines 11-21; Examples II-IX).

Claim 21 encompasses the method of claim 11, wherein said method further comprises the step of spraying, extruding, or slot coating said lotion onto said substrate. Hammons et al. specifically disclose spraying, extruding, or slot coating the lotion onto the substrate (page 22, lines 22-24; Examples III, V, VII, IX).

Claim 22 encompasses the method of claim 11, wherein said niacinamide is acidified niacinamide. Hammons et al. specifically disclose the use of acidified niacinamide (page 10, lines 13-14).

Claim 23 encompasses the method of claim 11, wherein said material of said premix solution is selected from the group consisting of glycerin, propylene glycol, and mixtures thereof. Hammons et al. specifically disclose the use of glycerine in the premix solution (page 13, lines 19-24; Examples II, III, and IX).

Claim 24 encompasses the method of claim 11, wherein said material of said premix solution is glycerin. Hammons et al. specifically disclose the use of glycerine in the premix solution (page 13, lines 19-24; Examples II, III, and IX).

Claim 25 encompasses the method of claim 11, wherein said lotion further comprises chitosan or chitosan derivative. Klofta et al. specifically disclose that the lotion should preferably include a skin care ingredient such as chitosan (paragraph [0059]).

Claim 26 encompasses the method of claim 21, wherein said premix solution is added to the carrier system at a temperature of about 60 to about 90 degrees C. Hammons et al. teach that the skin treatment solution is added to the carrier solution at a temperature of about 80°C (page 27, lines 9-11). Furthermore, Klofta et al.

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specifically disclose use of a mill when adding the predispersion to the petrolatum carrier at a temperature of about 77° C (Example 1; paragraph [0200]).

Claim 27 encompasses the method of claim 21, wherein said premix solution is added to the carrier system at a temperature of about 70 to about 90 degrees C. Hammons et al. teach that the skin treatment solution is added to the carrier solution at a temperature of about 80°C (page 27, lines 9-11). Furthermore, Klofta et al. specifically disclose use of a mill when adding the predispersion to the petrolatum carrier at a temperature of about 77° C (Example 1; paragraph [0200]).

The teachings of Hammons et al. and Klofta et al. are each directed to the formulation of lotions for application to absorbent articles such as sanitary napkins. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine their teachings by using the milling step of Klofta et al. to mix the premix solution and carrier system of Hammons et al, with the predictable result of obtaining a lotion having an average droplet diameter of the dispersed premix solution of less than about 100 microns, with a reasonable expectation of success. A person of ordinary skill in the art would have been motivated to do so to in order to break down the droplet size and disperse the droplets in the lotion, as suggested by Klofta et al.

Response to Arguments

The prior Office Action dated April 27, 2010, rejected claims 11-18 and 20-27 under 35 U.S.C. 103(a) as being unpatentable over Scavone (WO 02/069924) and

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Osborne et al. (U.S. Patent No. 6,716,441), and further in view of Kelly (U.S. Patent No. 5,264,205) for claim 17, and further in view of Sharma et al. (U.S. Patent No. 5,104,913) for claim 18 (pages 4-8).

In response thereto, applicant argues that Osborne et al. issued April 6, 2004, and thus qualifies as prior art only under 35 U.S.C. 102(e) because the instant application was filed February 27, 2004. Applicant asserts that the subject matter disclosed in Osborne et al. and the subject matter recited in the pending claims were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person, namely The Procter & Gamble Company. Applicant notes recorded assignments as evidence thereof. Thus, applicant asserts that Osborne does not qualify as prior art against any of the pending claims, pursuant to 35 U.S.C. 103(c)(1). Applicant traverses the rejection on other grounds as well. (pages 8-19).

Applicant's arguments and evidence regarding the use of Osborne et al. as prior art are found persuasive. Thus, the rejection of claims 11-18 and 20-27 under 35 U.S.C. 103(a) as being unpatentable over Scavone (WO 02/069924) and Osborne et al. (U.S. Patent No. 6,716,441), and further in view of Kelly (U.S. Patent No. 5,264,205) for claim 17, and further in view of Sharma et al. (U.S. Patent No. 5,104,913) for claim 18, is hereby withdrawn. Applicant's traversal and arguments on other grounds regarding the rejection are therefore moot and not considered herein.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL PALLAY whose telephone number is 571-270-3473. The examiner can normally be reached on Monday through Friday, 8:30 AM to 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MBP

/GINA C. YU/
Primary Examiner, Art Unit 1617